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### NOTICE OF ALLOWANCE AND FEE(S) DUE

21552

7590

12/03/2009

AUSTIN RAPP & HARDMAN 170 South Main Street, Suite 735 SALT LAKE CITY, UT 84101 EXAMINER

MARCETICH, ADAM M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 12/03/2009

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
Ī	10/599,708	07/27/2007	Heping Huang	3557.2.123	3051

TITLE OF INVENTION: PLASMA LIPIDS IN-VITRO FILTERING METHOD AND APPARATUS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	03/03/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

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10/599,708		07/27/2007	Heping Huang	3557.2.123	3051
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170 South Main Street, Suite 735				ART UNIT	PAPER NUMBER
SALT LAKE CITY, UT 84101			3761		
			DATE MAILED: 12/03/2009		

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	pplicant(s)		
	10/599,708	HUANG ET AL.			
Notice of Allowability	Examiner	Art Unit			
	Adam Marcetich	3761			
The MAILING DATE of this communication appeal all claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT R of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED or other appropriate comm IGHTS. This application is	in this application. If not included nunication will be mailed in due cours	se. <b>THIS</b>		
1. This communication is responsive to <u>09 September 2009.</u>					
2. ☑ The allowed claim(s) is/are <u>1-5,9 and 11-16</u> .					
<ol> <li>Acknowledgment is made of a claim for foreign priority una)</li></ol>	e been received. e been received in Applica	tion No	rom the		
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONN THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.		le a reply complying with the requirer	ments		
<ol> <li>A SUBSTITUTE OATH OR DECLARATION must be subm INFORMAL PATENT APPLICATION (PTO-152) which give</li> </ol>			CE OF		
5. CORRECTED DRAWINGS ( as "replacement sheets") mus	st be submitted.				
(a) including changes required by the Notice of Draftspers	on's Patent Drawing Revi	ew ( PTO-948) attached			
1)  hereto or 2)  to Paper No./Mail Date					
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date					
ldentifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).					
<ol> <li>DEPOSIT OF and/or INFORMATION about the depo attached Examiner's comment regarding REQUIREMENT</li> </ol>			the		
Attachment(s)					
1. Notice of References Cited (PTO-892)		Informal Patent Application			
2. Notice of Draftperson's Patent Drawing Review (PTO-948)		Summary (PTO-413), b./Mail Date			
3. Information Disclosure Statements (PTO/SB/08),		's Amendment/Comment			
Paper No./Mail Date 4. ☐ Examiner's Comment Regarding Requirement for Deposit	8. 🛛 Examiner	's Statement of Reasons for Allowand	ce		
of Biological Material	9.	<u>_</u> .			
/Adam Marcetich/	/Leslie Deak/				
Examiner, Art Unit 3761	Primary Exam	iner, AU 3761			

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### **DETAILED ACTION**

### **Priority**

Acknowledgment is made of applicant's claim for foreign priority under 35
 U.S.C. 119(a)-(d). A certified copy of parent Application No. China 200420021636.6,
 filed on 06 April 2004 has been received.

# Claim Interpretation

2. Examiner finds an enabling description of amended claims 1 and 9 in the specification, describing the claimed first, second and third films (¶ [0012], [0018], [0028]):

Layer	Pore size (microns)	Material	Function
Second	0.3		Filters bacteria and chyle-lipoprotein
First	0.3 – 0.65	Silicon oxide and optional multiple layers	Filters lipids
Third	0.2	Nylon	Filters foreign particles

## Response to Arguments

3. Applicant's arguments, see p. 7-17 filed 04 September 2009 with respect to the rejection(s) of claim(s) 1-9, 11-16, and 18-19 under 35 USC § 103 over Bomberger '809, Bomberger '776, Matkovich, Foltz, Jacobsen and Papillon have been fully considered and are persuasive. Therefore, the rejection is withdrawn.

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### Allowable Claims

4. Claims 1-5, 9 and 11-16 are allowed over the prior art of record.

#### Reasons For Allowance

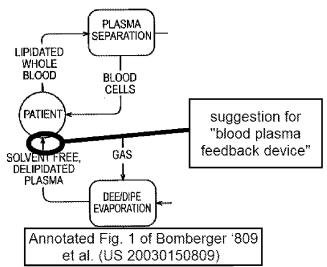
- 5. The following is an examiner's statement of reasons for allowance:
- 6. The closest prior art of record, Bomberger '809 et al. (US 20030150809) discloses an in-vitro blood plasma lipids filtering method and apparatus (¶ [0025], [0086], [0093]), comprising:
- 7. collecting blood from a patient by a blood collecting device (¶ [0108], Fig. 2, fluid source 28 including apheresis system);
- 8. separating blood plasma from the collected blood by a blood separating device connected to the blood collecting device (¶ [0093], [0114] and Fig. 2, centrifuge 86 separating blood plasma);
- 9. controlling pressure of separated blood plasma by a pressure control device (¶ [0115] and Fig. 2, sensors 96 controlling pressure);
- 10. passing the separated blood plasma through the blood plasma lipids filtering device for filtering out lipids of the separated blood plasma (¶ [0059], [0101]-[0102], Figs. 2, 3, HFC / hollow fiber contactor 18 filtering lipids);
- 11. flushing a blood plasma lipids filtering device (¶ [0092], flushing HFC);
- 12. wherein the blood plasma lipids filtering device comprises multi-layers of thin film membranes (¶ [0101], [0119], Figs. 3, 9, HFC 18 comprising multiple hollow fibers 20), of which:

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13. at least a first film is a membrane having filter aperture pores of about 0.3 to 0.65 microns and comprises a lipid absorptive material for filtering out lipids of the separated blood plasma ( $\P$  [0101]-[0102] and Fig. 3, HFC 18 comprising hollow fibers 20 having pores 26 sized up to 300 nm, or 0.3  $\mu$ m; overlapping claimed range of about 0.3 to 0.65  $\mu$ m; hollow fibers are substantially lipid absorptive, as indicated by their ability to allow lipids to diffuse through pores 26);

14. feeding the filtered blood plasma back to the blood of the patient (Fig. 1, delipidated plasma returned to patient). While Bomberger '809 does not explicitly disclose a blood plasma feedback device, Bomberger '809

suggests connecting to a patient since



the system returns delipidated plasma. See annotated Fig. 1.

- 15. However, Bomberger '809 fails to teach or fairly suggest alone or in combination the essential structures of the claimed device, such as at least one additional first film further interposed between the second and third films, and wherein the lipid absorptive material of the first film and the additional first film comprises silicon oxide pellets.
- 16. Bomberger '809 is entirely silent regarding silicon oxide pellets, and discloses only a first layer. Motivation is lacking to modify Bomberger '809 with an additional layer comprising silicon oxide pellets, since Bomberger '809 extracts lipids in HFC 18 with

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solvents. For example, Bomberger '809 flows extraction fluid and plasma through HFC to remove lipids from plasma (¶ [0107]). Additionally, modifying the HFC fibers with silicon oxide pellets would require restraining or holding layers. That is, silicon oxide pellets are granular or loose, and require additional materials to hold them in place. Therefore Bomberger '809 lacks the claimed additional first film, along with a suggestion to modify.

- 17. The claimed silicon oxide pellets are critical since they filter lipids from separated blood plasma by absorbing lipids to filter media (specification p. 4, ¶ [0020], "pure physics affinity with the natural adsorption method"). That is, the claimed invention removes lipids from the blood without solvents, or chemical reactions, by passing plasma over silicon oxide pellets. Bomberger '809 instead requires solvents that extract lipids.
- 18. Similarly, Bomberger '776 et al. (US 20060000776) discloses a system and method for removing lipids from plasma (¶ [0002], [0022], [0073], Fig. 2, system 10) comprising:
- 19. collecting blood from a patient by a blood collecting device (¶ [0082], Fig. 2, blood stored in fluid stored 14 prior to treatment);
- 20. separated blood plasma that enters a pre-filtered blood plasma bag (¶ [0082], [0110], Fig. 2, fluid source 14 containing plasma); and
- 21. flushing a blood plasma lipids filtering device connected to the pressure control device with saline solution from a saline solution treatment bag connected to an outlet of

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of about 0.2 mm).

the pre-filtered blood plasma bag (¶ [0110], priming delipidation system 10 using a saline fluid stored within saline fluid source 21).

- 22. However, Bomberger '776 also lacks the claimed second layer. Examiner cited Bomberger '776 as teaching a step of flushing with saline (¶ [0110] saline preferable because it is isotonic with plasma). However, Bomberger '776 fails to remedy the critical deficiency of Bomberger '809, namely the first film and additional first film comprising silicon oxide pellets. Bomberger '776 instead discloses a filter membrane comprising at most a single layer (¶ [0076], HFC's 16 comprising hollow fibers 20 each formed by a membrane), and lacks a suggestion to modify this filter membrane with silicon oxide pellets. Additionally, Bomberger '776 removes lipids with solvent (¶ [0076], [0077]), similarly to Bomberger '809. The claimed system instead removes lipids with silicon oxide pellets.
- 23. Also cited in the last Office Action, Matkovich et al. (US 5252222) discloses a filter for treating parenteral fluids (col. 3, lines 16-19), comprising:
- 24. a second film membrane having filter aperture pores of about 0.3 microns (col. 8, lines 32-41 and col. 7, lines 54-58, prefilter in examples 3 and 5 having pore rating of about 2 mm which substantially approximates the claimed range of about 0.3 mm), and 25. a third film membrane having filter aperture pores of about 0.2 microns and comprising nylon as a base material (col. 8, lines 32-41, hydrophilic nylon membrane with pore rating of about 0.65 mm, which substantially approximates the claimed range

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26. Here, Examiner cited Matkovich as teaching the claimed second and third films. However, Matkovich fails to remedy the deficiencies of Bomberger '809 and Bomberger '776, namely the first film and additional first film comprising silicon oxide pellets. Additionally, Matkovich solves a different problem than the claimed second and third layers. Matkovich removes microbes from nutritional solution with the two layers (col. 1, lines 22-40), while the claimed invention filters bacteria and chyle-lipoprotein with a second layer and filters foreign particles with the third layer. Additionally, Matkovich teaches away from absorbing lipids, since the nutritional solutions contain emulsified lipids intended to bypass a filter (col. 1, lines 36-40).

- 27. Another reference of record, Papillon; Jean et al. (US 5348533) discloses a blood processing system (col. 1, lines 7-10, col. 3, lines 22-29), comprising:
- 28. a centrifuge (col. 3-4, lines 65-9, Fig. 1, centrifuge 40 having stationary part 12 and bowl 10),
- 29. an automatic weight/volume detection device for transmitting a signal that triggers a stop response to the blood separating device and the blood collecting device when the blood plasma bag is full (col. 4, lines 29-33, Fig. 1, digital weighed W2 providing signal to processor 20).
- 30. Examiner cited Papillon to remedy a deficiency of an automatic weight/volume detection device. However, Papillon entirely lacks a multi-layer filter, especially a multi-layer filter comprising a first film and additional first film comprising silicon oxide pellets. Papillon instead separates blood with a centrifuge, and fails to suggest any filter

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element (col. 3, lines 44-47, system comprising blood component separator and no filtering devices).

31. Also cited in the previous Office Action, Cham (US 4895558) discloses a method and device for removing lipids from plasma (col. 1, lines 7-10), comprising:

- 32. collecting blood from a patient by a blood collecting device (col. 3, lines 31, 56-61, Fig. 6, drawing needle);
- 33. separating blood plasma from the collected blood by a blood separating device connected to the blood collecting device (col. 3, lines 32, 56-61, Fig. 6, disposable centrifugal separator);
- 34. a saline solution treatment bag (col. 8, lines 40-44 and Fig. 6, replacement fluid solution container), and
- 35. a waste saline solution bag (col. 8, lines 8-18 and Fig. 6, waste bag),
- 36. However, Cham does not teach the critical first film and additional first film comprising silicon oxide pellets. Also, Cham extracts lipids with solvent (col. 3, lines 33-35, 62-68, Fig. 6, plasma / solvent mixer / delipidation unit) similarly to Bomberger '809 and Bomberger '776. Therefore Cham does not contemplate filtering lipids from separated blood plasma with an absorbent filter.
- 37. Also of record, Foltz et al. (US 5401466) teaches a separation device for lipids (column 3, lines 27-34), comprising:
- 38. a lipid absorptive material comprising silicon oxide pellets (col. 6, lines 25-44, especially lines 32-36).

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39. However, Folz does not teach an additional layer comprising silicon oxide pellets. to clarify, Folz teaches at most a single layer of silicon oxide pellets (Fig. 1, layer 1 of glass fiber and porous silica) and therefore fails to remedy the deficiencies of the above cited references. Additionally, Folz filters lipids for testing or diagnosis, not a high-volume hollow-fiber membrane (col. 3, lines 60-67). Therefore, the filters of Bomberger '809 and Folz are substantially incompatible, and one having ordinary skill in the art would not be motivated or enabled to modify the single-layer filter of Bomberger '809 with a silicon oxide pellet layer of Folz.

- 40. Not previously cited, Gorsuch; Reynolds G. F. et al. (US 5152743) discloses a system for reducing blood cholesterol (col. 1, lines 10-13, col. 3, lines 9-16, col. 4, lines 49-52, Fig. 1, apparatus 10), comprising:
- 41. collecting blood from a patient by a blood collecting device and separating blood plasma from the collected blood by a blood separating device connected to the blood collecting device (col. 4, lines 52-57, Fig. 1, plasma separation apparatus 10 removing plasma from vein 11); and
- 42. passing the separated blood plasma through a blood plasma lipids filtering device for filtering out lipids of the separated blood plasma (col. 4, lines 57-61, col. 7, lines 12-24, Fig. 1, cholesterol removal filter 13).
- 43. However, Gorsuch fails to teach or fairly suggest alone or in combination the critical silicon oxide layers. Instead, Gorsuch filters cholesterol with hollow fibers (col. 9, lines 34-56, filter fibers 38, 38' comprising polymer). Therefore Gorsuch fails to remedy the deficiencies of the above cited references.

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44. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### **EXAMINER'S AMENDMENT**

- 45. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
- 46. Authorization for this examiner's amendment was given in a telephone interview with Thomas M. Hardman on Monday, 2 November 2009.

#### Conclusion

47. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

♦ Fissell, William H. IV et al. US 20040124147

♦ Atkin J. et al.
US 4950224

♦ Atkin J. et al.
US 5152743

♦ Gorsuch, Reynolds et al. US 20040050788

48. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Art Unit: 3761

Adam Marcetich

Tel (571)272-2590

Fax 571-273-2590

49. The Examiner can normally be reached on 8:00am to 4:00pm Monday through

Friday.

50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

51. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/

Examiner, Art Unit 3761

/Leslie R. Deak/

Primary Examiner, Art Unit 3761

16 November 2009